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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,900

06/23/2006

Francois Schutze

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

02/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,900	Applicant(s) SCHUTZE ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/7/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Reply filed December 7, 2009 is acknowledged. Claims 12-16 and 21 remain under consideration.

A Substitute Specification filed December 7, 2009 is further acknowledged.

The objection and rejections set forth in previous Office Actions that are not herein reiterated are withdrawn. The following objection and rejections constitute the only objection and rejections that are presently applied to the instant claims.

The disclosure is objected to for the following informality:

In claim 12 "Barrett's" is misspelled.

Appropriate correction is required.

Claims 12-16 and 21 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,402,593 in the last Office Action. The instant claims encompass a medicament comprising enantiomers of tenatoprazole for use in the treatment of gastroesophageal reflux disease. Claims 12-16 and 21 were also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 9 and 12-14 of U.S. Patent No. 7,034,038. The co-pending claims are drawn to compositions comprising enantiomers of tenatoprazole to treat gastroesophageal reflux disease and Barrett's esophagus.

In the last Office Action claims 12-16 and 21 were also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-20 of copending, now allowed, Application No. 11/344212. The instant

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claims encompass a medicament comprising enantiomers of tenatoprazole for use in the treatment of Barrett's esophagus.

Applicants choose to hold these obviousness-type double patenting rejections in abeyance.

The rejections of record on the ground of nonstatutory obviousness-type double patenting are maintained.

Claims 12-16 and 21 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. The claims are directed to treating nocturnal gastroesophageal reflux or Barrett's esophagus comprising administering tenatoprazole. According to the instant specification, methods of prevention are encompassed in the present claims. See page 6, paragraph 21. The present specification does not reasonably provide enablement for said methods within the full scope of the claims.

According to The Merck Manual, which was cited for evidentiary purposes only, the treatment of Barrett's esophagus subsequent to the administration of tenatoprazole would not have been predictable. See the discussion under Esophageal Cancer, page 321. As such, one skilled in the medical arts would not have readily accepted an assertion that the administration of tenatoprazole predictably results in prevention of nocturnal gastroesophageal reflux or Barrett's esophagus.

The rejection of record under 35 U.S.C. 112, first paragraph, is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 23, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614